



**REVIEW OF A SELF-CONTAINED
SELF-RESCUER PROCUREMENT CONTRACT
AND THE PORTAL-PACK RECALL
FOR THE MINE SAFETY AND
HEALTH ADMINISTRATION**

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EXECUTIVE SUMMARY

At the request of the Assistant Secretary for Mine Safety and Health, the Office of Inspector General conducted an evaluation of two similar complaints that involved the Mine Safety and Health Administration's regulation and procurement of self-contained self-rescuer devices. Miners wear self-contained self-rescuers to generate oxygen when the air becomes toxic. The first issue was raised in a letter to a Congressman in which many complaints were made regarding the Mine Safety and Health Administration (MSHA), including a concern that MSHA had exercised favoritism in entering into a sole-source procurement contract for self-contained self-rescuers (SCSRs) with the Mine Safety Appliance Company (MSA).

The second complaint was received from the United Mine Workers of America (UMWA) and included two accusations. First, UMWA officials stated that certain MSHA actions in conducting the recall of MSA's Portal-Pack SCSR were intended to protect the company's economic interests. Second, UMWA expressed concern that MSHA had mishandled many aspects of the Portal-Pack recall.

Neither our review of MSHA's procurement of SCSRs from MSA nor our evaluation of the Portal-Pack recall found any evidence indicating collusion or favoritism between MSHA and MSA. However, to improve the effectiveness of program operations and enhance stakeholder confidence in the agency, the following issues need to be addressed. Sole source procurement and the certification, audit and recall of SCSRs merit attention by MSHA. Since responsibilities for the certification, audit and recall of SCSRs are shared with the National Institute for Occupational Safety and Health (NIOSH), cooperative actions by the two agencies will be required to accomplish all of the actions we are recommending.

With respect to MSHA's procurement of 400 SCSRs from MSA, we concluded that the agency's use of the sole-source process was not fully justified in this instance and have recommended that procurement practices be reviewed with the objective of expanding the use of competitive bids and ensuring conformance with Department of Labor regulations.

The timeliness and consistency of MSHA communications with stakeholders could be improved to increase the confidence of the mining community in the regulation of SCSRs. Specific communication related issues warranting MSHA's attention include timely and accurate notifications of product defects, policies and procedures to clarify responsibilities for disseminating information, and effective coordination of official positions with NIOSH.

Our review identified other MSHA opportunities for implementing programmatic improvement in quality assurance, data collection of mine information, revision of regulatory standards and procurement practices. Specifically, clarification of MSHA and NIOSH roles in ensuring manufacturer compliance with quality assurance in an amended memorandum of understanding offers significant promise in reducing the number of SCSR recalls. An additional opportunity for agency improvement exists in increasing the frequency of data collection from mines on SCSR usage. Revisions to standards for certification, audit and training could reduce the number of recalls, improve surveillance and ensure that miners receive adequate SCSR training.

This report contains MSHA's response to our draft report. The MSHA response is found in the body of the report and in its entirety in Appendix B. MSHA agreed with all our recommendations and we consider them resolved. We are awaiting written confirmation of MSHA's corrective actions so that we can close the recommendations.

Due to the close regulatory relationship that the Department of Labor shares with NIOSH on SCSRs, we also provided NIOSH with our draft report for comments. Since our report was addressed to MSHA, we have not included NIOSH comments in the body of this report. However, the NIOSH recommendations for this report are included in Appendix C. Our response to the NIOSH comments is located in Appendix D. We have included many of the NIOSH comments in our report.

I. INTRODUCTION

In response to a Congressional inquiry and a request by MSHA management, the Office of Inspector General's Office of Analysis, Complaints and Evaluations, conducted an evaluation of an MSHA sole-source procurement contract for SCSRs and the agency's handling of the Portal-Pack recall. The purpose of our review was to conduct an evaluation of two similar complaints that involved the Mine Safety and Health Administration's regulation and procurement of SCSRs. The objectives of our review were to determine whether: (1) MSHA's actions with respect to the procurement and the recall of SCSRs were consistent with applicable laws, regulations and procedures; (2) MSHA's procurement or recall actions financially benefitted a specific company or created the appearance of such favoritism; and, (3) opportunities exist for improving the certification, audit and recalls of SCSRs.

This review was conducted in two phases. Phase one, addressing a complaint of an exclusive contractual relationship between MSHA and MSA, was initiated on February 5, 1997, and completed on November 1, 1997. Phase two, evaluating MSHA's handling of the Portal-Pack recall and concerns regarding commercial protection of MSA, was initiated on November 10, 1997. This report summarizes all evaluation work conducted on MSHA's sole-source contract complaint and the recall of the Portal-Pack.

II. BACKGROUND

The first complaint alleged that the Mine Safety and Health Administration was favoring certain companies in a sole-source procurement contract. This issue was raised in a 1996 letter from Congressman Dan Schaefer to the Secretary of Labor. On September 13, 1996, the CSE Corporation sued MSHA for injunctive relief, protesting its sole-source procurement contract with MSA. MSHA subsequently agreed to reduce the size of the procurement and to conduct all subsequent procurement using a competitive bid process.

By a memo dated November 3, 1997, the Deputy Assistant Secretary for Mine Safety and Health informed the Office of Inspector General of issues raised by an administrator of the UMWA. A letter on October 20, 1997, from the UMWA to the Assistant Secretary, complained that MSHA had mishandled the

recall of Portal-Packs manufactured by MSA. An allegation made to the Deputy Director of Technical Support by an official of the UMWA Department of Occupational Health and Safety at an October 28, 1997 meeting, indicated that MSHA was favoring MSA. This complaint was repeated in an October 31, 1997 telephone call between the UMWA and the Deputy Assistant Secretary.

The Mine Safety and Health Administration's mission is to protect miner safety. MSHA is authorized to conduct regulation of the mining industry under the "Federal Mine Safety and Health Act" of 1977, in Public Law 95-164. Sections specific to SCSR regulation are contained in the Code of Federal Regulations (CFR).

CFR 75:7514 requires that all persons who enter a mine have a SCSR available to them that will provide one hour of oxygen when it is donned and activated. Many SCSRs chemically generate oxygen when started, although some SCSRs contain compressed oxygen. SCSRs are worn on coal miners' belts, mounted on mining machinery, cached within the mine and stored above ground.

MSHA conducts certification and approval of SCSRs in collaboration with the National Institute for Occupational Safety and Health (NIOSH). A memorandum of understanding, dated May 4, 1995, generally describes this relationship. NIOSH has the lead in insuring that SCSRs pass set scientific standards required in Title 42 CFR Part 84.1-84.1158 and MSHA is responsible for regulating mine compliance. Although MSHA and NIOSH have joint responsibility for quality assurance, NIOSH also takes the lead in certifying manufacturing quality control.

The certification and audit programs are highly technical and both agencies employ scientific experts at various centers. MSHA's two sites for handling technical evaluation and oversight of SCSRs had been the Approval and Certification Center in Triadelphia, WV, and the Pittsburgh Safety and Health Technology Center in Bruceton, PA. Recently, technical evaluation and oversight of SCSRs was transferred to MSHA's Bruceton facility. The two primary NIOSH facilities responsible for SCSR testing are the Pittsburgh Research Labs (PRL) in Bruceton, PA, and the Certification and Quality Assurance Branch (CQAB) in Morgantown, WV, at the Appalachian Laboratory for Occupational

Safety and Health. The CQAB has the authority and responsibility to interpret and implement the 42 CFR 84 design, quality assurance and performance regulatory standards. In addition, CQAB conducts investigations to determine SCSR compliance with certification standards. The NIOSH PRL is responsible for human physiology research, SCSR technology research, environmental testing and evaluation of field deployed SCSSRs.

SCSSRs undergo testing and certification and must meet MSHA and NIOSH standards before they can be sold as approved safety devices. As part of the certification process, manufacturers submit a quality control plan describing how quality will be ensured. Ensuring quality control processes is an integral part of the certification.

SCSSRs have a set length of service or shelf-life. The Portal-Pack SCSR model manufactured by MSA has dates stamped on the housing of the unit showing a date of production, a serial number, and an in-service date that controls when the unit must be removed from service. The in-service date begins when the unit is deployed into the mine environment. Currently, the manufacturer determines the service life.

MSHA and NIOSH conduct a joint testing or audit program of SCSR models that have been approved and sold to mines. The audit, which NIOSH funds, samples from a proportional but not a statistically representative sample of SCSR models that are in service. The NIOSH group at PRL tests SCSSRs to verify that they are working according to established standards. The audit program has been credited by MSHA and NIOSH with being highly effective in discovering SCSR deficiencies.

MSHA has expended considerable resources during the 1980s and 1990s certifying and overseeing company recalls of SCSSRs and other types of mining equipment. Section CFR 75.1714-3.d gives MSHA authority to remove from service any SCSR that does not meet specified test requirements and ensures that repairs are completed by the manufacturer. Recalling SCSSRs has become a regular ongoing part of MSHA's operations.

The chronology of events that occurred in the Portal-Pack recall is briefly summarized as follows. During a joint

MSHA/NIOSH audit in March 1997, KO2 chemical dust was identified in the breathing tube of two SCSRs. The KO2 chemical is used to generate oxygen when activated.

Continued investigation by MSHA and NIOSH of the chemical dust problem led to the classification of a critical defect on June 27, 1997. MSA was notified to take corrective actions and to stop sale of the Portal-Pack as a certified device. MSA proposed two corrective action plans which were rejected by NIOSH/MSHA as inadequate. Finally, MSA proposed an interim plan involving a new donning procedure, corrective retraining of miners on the new operating procedure and daily visual inspection of Portal-Packs to find any dents or abrasions that could be responsible for loose dust in the device. The revised donning procedure called for the miner to blow into a mouthpiece three times in order to clear away any dust that may have migrated up into the breathing tube from the chemical bed. This corrective action plan, along with a stop-sale of additional Portal-Packs by MSA, was accepted by MSHA/NIOSH as an interim solution, while MSA attempted to fully resolve the chemical dust problem and other identified deficiencies.

MSA distributed a user safety notice along with an instruction manual on the revised donning procedure on July 11, 1997, to customers it was able to identify. Because MSA was not able to identify all customers and stakeholders, not everyone received notification of the Portal-Pack recall. The notice on conducting training within 30 days was stated as a recommendation and not as a regulatory requirement.

MSHA subsequently distributed an advisory letter to district managers on July 18, 1997, stating that training was to be conducted within 30 days of the distribution of the user safety notice. No direct notification was made to the mines and other stakeholders by MSHA until the issuance of a Program Information Bulletin on November 13, 1997, following the resolution of several policy issues. MSHA requested that all inspection personnel in the mine districts be alerted to the user safety notice and asked that inspectors communicate conditions of the recall to the mines.

Continued testing of the Portal-Pack during July 1997, found that dust contamination was occurring at a much higher frequency than originally estimated. Of 59 Portal-Packs examined, 11 (19 percent) were found to contain KO2 dust in the

breathing tubes or mouthpieces. In addition, problems discovered with the firing mechanism and a leak in the breathing tubes remained unresolved. In response, on August 8, 1997, NIOSH/MSHA mandated that MSA conduct a recall of all Portal-Packs.

On August 15, 1997, MSA agreed to recall the Portal-Packs and replace them with their new Life-Saver 60 SCSR. Some defects with the new model had been recently discovered, but were addressed by MSA in a revised design and manufacturing process. MSA committed to an ambitious schedule of replacing the Portal-Pack that depended on quick approval of the corrective changes to the Life-Saver 60 by NIOSH and a replacement estimate of 5,490 Portal-Packs.

On August 22, 1997, MSHA, NIOSH and MSA met to discuss the problems of the Life-Saver 60. At this meeting it was determined that previous problems relating to the breathing bag leaks of the Life-Saver 60 had been identified, that a corrective plan had been developed and that there was not a significant impediment posed to the replacement of Portal-Packs with the Life-Saver 60. Subsequent delay in approving the corrective changes to the Life-Saver 60 by NIOSH and a far greater number of Portal-Packs in mines than had been estimated, combined to prevent timely replacement on schedule.

UMWA officials state that they became aware of the severity of the problems surrounding the recall in late September. The UMWA requested a meeting with MSHA and NIOSH that was held on October 28, 1997. At this meeting, it appeared that there was a lack of regulatory consensus regarding the adequacy of the interim plan and the Life-Saver 60 replacement. This moved the UMWA to file for an injunctive action on November 17, 1997. On November 18, 1997, NIOSH/MSHA decertified the Portal-Pack and required that MSA accelerate the completion of the recall even if it required replacement with SCSRs from other companies. MSA responded by offering mine operators a payment of \$365 for each Portal-Pack replaced by an equivalent SCSR. Other manufacturers also began to produce SCSRs to meet the sudden demand for replacements. MSA acknowledged that their original estimate of the Portal-Packs deployed in the mines was inaccurate, and that 7,533 units needed immediate replacement.

III. METHODOLOGY

Our evaluation had two phases. Our review first examined the June 1996 MSHA sole-source procurement contract for SCSRs from MSA. We then reviewed regulatory activity regarding the MSA Portal-Pack recall.

By using a mixed methods approach, we were able to triangulate our findings. An evaluation of this type collects information using different methods. This method improved measurement and enhanced analytic findings.

The evaluation first reviewed company product information, federal regulations, and MSHA policies and procedures. Structured interviews were conducted with senior officials of major groups of the coal mining communities. These groups included: federal regulatory agencies, a union, manufacturers of SCSRs, and professional associations.

Initial interviews with senior management from MSHA summarized the allegations and the problems encountered with the Portal-Pack recall. Interviews were then conducted with NIOSH officials at the PRL and at the CQAB. Finally, interviews were conducted with MSA and MSHA personnel at the Approval and Certification Center and the Quality Assurance Division (QAD) during the first two weeks of January 1998.

We reviewed 36 agency files covering QAD handling of SCSR problem issues over the last 12 years. Of the 36 cases, we selected 13 recall cases for comparison to the Portal-Pack. Our criteria for selection included cases that had a recall or retrofit action. Our analysis of cases provided comparative information to assess the Portal-Pack recall, although some gaps in MSHA's case documentation were encountered. Descriptive statistics of SCSR recalls were developed.

A data collection instrument was used to facilitate review of archived records. The focus of the instrument was to collect data on key recall characteristics. Key characteristics included the time that elapsed for completion of the recall, methods of communication, and noted abnormalities in established procedures or regulations. The findings on other regulatory efforts were then compared to the characteristics collected on the Portal-Pack recall for comparative analysis.

We conducted our review according to the *Quality Standards for*

Inspections published by the President's Council on Integrity and Efficiency.

IV. Findings, Conclusions and Recommendations

We found that although MSHA complied with DOL regulations in executing a sole-source contract with MSA, the use of the sole-source method for procuring the equipment could not be fully justified. The contract resulted in a protest of the award by the CSE corporation. This protest was settled to CSE's satisfaction.

MSHA did not favor MSA in the handling of the Portal-Pack recall. The UMWA's concern that MSHA was protecting the commercial interests of the Mine Safety Appliance Company (MSA) was based primarily on two observations. First, by delaying and limiting the negative impact that would have ensued from swiftly distributing a Program Information Bulletin (PIB) and by giving MSA an extended time-frame to complete the recall, it appeared to the UMWA that MSHA was acting to protect the commercial interests of MSA. MSA was in the process of distributing the new model Life-Saver 60. Second, the failure to immediately survey other SCSR manufacturers for inventory or manufacturing capacity that could have been directed toward quick replacement of the Portal-Pack early in the recall appeared suspicious to the UMWA.

OIG found that the distribution of a PIB for a recall can not be used to accurately assess favoritism. While a PIB was issued in a delayed manner in this case, only 30 percent of the recalls we reviewed were publicized to the mining community through the use of PIBs. A comparison of time-frames for the completion of other SCSR recalls also does not provide conclusive evidence that MSA's recall schedule was unduly extended, as factors such as the severity of the defect identified and the estimated percentage of units affected would require consideration. MSHA distributed a PIB concerning the Portal-Pack recall on November 13, 1997.

We found that seven months elapsed between the start of the Portal-Pack investigation and the distribution of the November 13, 1997 PIB. This elapsed time was not long in comparison to other recalls examined. We found the length of time taken to distribute a PIB from the start of an investigation ranges from 2 to 25 months. The time-frame needed depends on the complexity of the defect.

MSHA officials stated that they typically undergo a three stage process in conducting recalls and issuing a PIB. In the first stage, which is usually short, the problem is identified. In the second stage, the scope of the problem is determined which can take significant periods of time. In the third stage, MSHA determines and implements the actions necessary to address the problem. Decisions regarding the issuance and timing of a PIB or the use of alternative means of communication with the mining community are predicated on the scope of the problem and other considerations.

The completion of MSA's recall was delayed by several factors. In particular, NIOSH was unable to accomplish an expedited certification of design changes for the improved Life Saver 60, intended as the replacement for the defective Portal-Packs. Following UMWA legal action, MSHA decertified the Portal-Pack and accelerated the MSA recall, which required MSA to replace the Portal-Pack SCSRs with models manufactured by other companies, an action rarely noted in the other recalls we reviewed. In addition, compliance with firm MSHA regulation culminating in decertification was costly for MSA. The General Manager of MSA's Safety Product Division calculated that the combined total cost to MSA of the Portal-Pack recall was \$5 million.

OIG identified some unique findings in the Portal-Pack recall. We found that MSA's early estimate of the number of Portal-Packs in use in the mines was significantly inaccurate. The actual number of Portal-Packs needing replacement exceeded the original estimate by 37 percent. There was a pattern of inaccurate estimates across other recalls and retrofits examined that also underestimated the number of SCSRs in the mines from 20 to 28 percent.

We also found that MSHA did not independently verify the inventory or manufacturing capacity of other SCSR companies early in the recall. However, MSHA rarely took this action in other recalls. The fact that MSHA did not initially survey other sources of suppliers for replacement SCSRs does not support a conclusion that MSHA favored MSA or improperly handled the Portal-Pack recalls.

While this report focuses primarily on recommendations to improve MSHA's regulation of SCSRs, it also has potential application to other areas of MSHA operations. Several themes

applicable to other MSHA areas emerged from our analysis. The recommendations made in our review originate from analysis of interviews and comparison of the Portal-Pack to other MSHA recall and retrofit actions.

1. Procurement Contract

MSHA complied with Federal and Department of Labor (DOL) regulations for non-competitive procurement by announcing the agency's intent in June 1996, to award a sole-source contract for SCSRs to MSA in the Commerce Business Daily (CBD) and by requesting the approval of DOL's Procurement Review Board (PRB). However, MSHA's use of the sole-source process was not fully justified, although no evidence supported an exclusive contractual relationship with MSA. CSE did file a protest against the contract award, which was settled in its favor by changing the size of the contract and emphasizing future competitive contracting practices.

MSHA was aware from both experience and research that a voice amplification feature on SCSRs was needed to prevent inhalation of CO during emergencies. MSA was the only company to address this need. On June 21, 1996, MSHA announced in the CBD its intent to award MSA a sole-source contract to produce a new, improved SCSR model. MSHA's rationale for the sole-source award, which was articulated to the PRB, was that MSA could produce a significantly smaller device than was currently available, and that MSA's SCSR incorporated a "voice amplification" capability which would allow a user, hands-free communications ability in the event of an emergency. The MSA SCSR was in the final stages of testing and expected to be approved shortly by MSHA and NIOSH for manufacture.

MSHA was also aware that an MSA competitor, the CSE Corporation, was testing a smaller and lighter version of the SCSR. Although CSE was the manufacturer of SCSRs currently in use by MSHA inspectors, the company's next generation prototype

did not include a voice amplification device which MSHA had stressed to the PRB was required. The PRB approved MSHA's request to purchase the MSA SCSR sole-source, at a contract value of \$578,799.

On September 13, 1996, CSE submitted a protest of the MSA sole-source award to the General Accounting Office (GAO), on the basis that MSHA failed to consider its prototype SCSR, which CSE claimed was smaller and lighter than the MSA prototype. CSE also claimed that its SCSR could have been adapted to incorporate a voice amplification device, had the company been made aware of MSHA's technical specifications for a next generation SCSR through a competitive bid announcement. CSE withdrew its protest with GAO after MSHA agreed to reduce the number of MSA SCSRs planned for use in the field by 50 percent and to make future procurement of SCSRs on a competitive basis.

Because MSHA has previously purchased SCSRs from CSE and continues to use CSE's SCSRs in its inventory, we do not conclude that MSHA has an exclusive sole-source relationship with MSA. However, MSHA erred in assuming that a firm like CSE, whose new prototype did not initially incorporate voice amplification, could not adapt its prototype(s) to meet MSHA's specifications. Obviously, CSE officials considered their company capable of producing a SCSR that met MSHA's requirements and expected the opportunity to compete.

Recommendation

We recommend that the Assistant Secretary for Mine Safety and Health ensure that MSHA:

1. Review sole-source procurement practices to expand the use of competitive bids and ensure conformance with DOL regulations.

MSHA Response

"We agree that the Mine Safety and Health Administration (MSHA) should review sole-source procurement practices to expand the use of competitive bids and ensure conformance with the Department of Labor (DOL) regulations. MSHA has always and will continue to foster competition to the maximum extent

possible by awarding contracts based on full and open competition. In the case of sole-source procurement actions, any proposed contract in excess of \$25,000, to be awarded on the open market, is synopsisized in the Commerce Business Daily (CBD). The purpose of the CBD announcement is to afford other offerors the opportunity to make the MSHA contracting officer aware of an equivalent product or service that their firm/organization has to offer. When that situation occurs, the MSHA contracting officer then affords that firm/organization the opportunity to make an offer by providing them with a solicitation document, in accordance with the requirements of both Federal and DOL Acquisition Regulations."

OIG's Conclusion

On the basis of MSHA's response, we consider this recommendation resolved. To close this recommendation, we would appreciate receiving a copy of the memorandum indicating completion of a review of sole-source procurement practices to expand the use of competitive bids and ensure conformance with the Department of Labor (DOL) regulations.

2. Communications

The timeliness and consistency of MSHA communications with stakeholders could be improved to increase the confidence of the mining community in the regulation of SCSRs. Specific communication related issues warranting MSHA's attention include timely and accurate notifications of product defects, policies and procedures to clarify responsibilities for disseminating information, and effective coordination of official positions with NIOSH. The following sections summarize the results of our review of communications related issues.

A. Notification of Product Defects

The methods currently in use by MSHA for communicating information about product defects did not ensure that all appropriate parties received timely notification about problems identified and remedial actions. During the Portal-Pack

recall, MSHA initially relied on a user's notice distributed by the manufacturer which did not reach all industry officials in need of the information. While the Program Information Bulletin (PIB) issued four months later was distributed widely across the industry and provided comprehensive information, this method of communication was not effective for instructions requiring prompt implementation. MSHA generally used a variety of communication techniques during the recalls we reviewed, and the delayed issuance of the PIB during the Portal-Pack recall was primarily attributable to the complexity of the policy issues involved. However, the communication gaps we noted highlight the need for MSHA to develop methods for rapidly disseminating preliminary information about problems and necessary responses and for obtaining manufacturers' input.

MSHA's reliance on the July 11, 1997 user's notice sent by MSA to notify the mining community of problems with the Portal-Packs and the need for training on new donning procedures did not reach all intended recipients. As discussed in greater detail in our finding regarding information resources, MSA did not have information concerning the location of over 2,000 Portal-Packs and it is, therefore, unlikely that all mines which had purchased these units received the user's notice. In addition, MSA's address list was comprised of the company's contacts at the mines, such as the procurement officer, and did not include all mine safety officers and certified SCSR trainers. As a result, all affected miners did not receive the supplemental training recommended in the user's notice in a timely manner.

A PIB was distributed by MSHA to an extensive list of industry officials on November 13, 1997, after additional technical and policy issues were addressed, to provide comprehensive information about the product defects and corrective actions required. PIBs are advisory letters that MSHA mails to program policy manual holders and other interested stakeholders to alert them to urgent issues in mine safety. PIBs often communicate important recall information and have manufacturer recall notices attached which are critical to ensuring miner safety. PIBs have a per issue distribution ranging from 10,000 to 40,000 copies, depending on the subject. In determining whether to communicate product defect information in a PIB and in the timing of the bulletin's release, MSHA balances the nature and scope of the problem against the risk of undermining confidence in the device among the mining community. For

example, MSHA did not release the PIB concerning the Portal-Pack recall until policy questions regarding decertification and the availability of replacement models, among other issues, were resolved and complete information could be disseminated. As illustrated by the Portal-Pack recall, the purpose of a PIB and policy matters entailed in the publication of these bulletins, restrict their usefulness as a means for notifying those who require immediate information.

While some stakeholders, particularly the UMWA, were of the opinion that MSHA relied primarily upon PIBs to communicate information regarding product defects, our review did not confirm this presumption. UMWA officials indicated that they expected timely distribution of PIBs to alert mine owners, miners and other key industry members of product defects and required actions. In view of their expectations, UMWA officials were concerned that MSHA was limiting information in order to protect MSA's economic position. However, our analysis found that PIBs were not MSHA's principal means of communicating information about product defects and were in fact, generated in only 30 percent of the recalls examined. Manufacturers' notices, approved by MSHA, have frequently been used to advise industry officials of defects identified, actions to be taken and other important information.

MSHA's communications and relations with SCSR manufacturers could also be enhanced by establishing an accelerated review and comment process prior to the release of information concerning product defects. A manufacturer interviewed complained that an issued PIB did not clearly distinguish the company's SCSRs from counterfeit units in which defects had been identified, so that its commercial reputation was unnecessarily damaged. Although MSHA currently tries to get feedback on PIB drafts before release, there is inconsistency in this effort. A consistently applied process for seeking stakeholder comments on draft PIBs within a quick response framework could reduce the potential for errors and avoid any perceptions of disparate treatment. MSHA officials concurred at the exit conference with the need for a new process, preferably under the responsibility of the agency's field managers, to extend preliminary notification about product defects identified and immediate actions required to those industry officials most directly affected. Industry members in need of prompt notification include mine owners and

operators, safety officers, miners and their representatives and, depending upon the circumstances, might also include other groups such as certified SCSR trainers. MSHA officials were also receptive to offering the responsible SCSR manufacturer an opportunity to rapidly review and provide comments on proposed MSHA notifications concerning product defects.

B. Policy and Procedures

As part of our review, we examined policies and procedures at the MSHA Approval and Certification Center (A&CC) as well as the National Office, to assess the agency's guidance regarding communications with stakeholders. National Office policies and procedures do not specifically address communications on SCSRs. Similarly, A&CC policies and procedures pertaining to recalls did not discuss when stakeholders should be notified of product defects, recalls or the methods of notifications, and A&CC staff expressed ambiguity over these questions. For example, the former A&CC Chief had been briefing important external stakeholders both formally and informally, but this practice lapsed after the selection of a new Chief, who expected that National Office management controlled such contacts. The resulting decrease in communications with key stakeholders may have generated some of the concerns brought to our attention.

MSHA management officials stated that they informed UMWA officials of on-going problems with the Portal-Pack in telephone conversations. The UMWA officials, however, did not consider that they were fully informed of the severity of the Portal-Pack deficiencies in a timely manner. Although we are not able to conclusively determine the extent of information shared with the UMWA, MSHA officials were aware by the time of our review, that communication had been inadvertently decreased following the appointment of the new A&CC Chief.

C. MSHA and NIOSH Communication

Coordination between MSHA and NIOSH could be improved to ensure that officials of both agencies clearly communicate a consistent Federal position during meetings with industry officials and other external stakeholders. Effective coordination also includes ensuring that commitments significant to the other agency's programs are fulfilled and, when completion on schedule is not possible, revised timetables are prepared jointly.

Inconsistent positions and misleading information on the Portal-Pack were presented to the UMWA at a meeting on October 28, 1997, according to our interviews with the Director of the Pittsburgh Research Lab, other NIOSH technical experts and MSHA personnel. Problems with the presentation occurred because one NIOSH technical expert did not coordinate his positions with other NIOSH officials or MSHA. Specifically, on October 24, 1997, the UMWA requested that the Director of the Pittsburgh Research Labs provide a specific technical expert for the October 28 meeting in order to discuss technical findings of field audits conducted on the Portal-Pack. Subsequently, the Director contacted the technical expert, who was the supervisor of the field audit program that initially detected the defects with the Portal-Pack, and authorized his attendance at the meeting with the UMWA.

The focus of the meeting was not to debate scientific opinion but, according to an October 1997 letter from the Assistant Secretary for Mine Safety and Health, it was to brief the UMWA on the MSHA/NIOSH handling of the recall. No effort was made by the technical expert at the Pittsburgh Research Laboratory to coordinate his presentation either with the NIOSH CQAB staff or with MSHA officials responsible for the recall. At the October 28, 1997 meeting, the NIOSH technical expert presented opinions on the safety of the recall plan that extended beyond his direct knowledge and made misleading statements regarding the facts. As a result, the NIOSH/MSHA regulatory collaborative effort appeared to lack consensus in how to best address the problems of the Portal-Pack.

Although there is room for disagreement based on scientific differences of opinion, we found that the lack of coordination regarding a joint official position undermined the image and authority of both agencies. While MSHA was not responsible for conflicting NIOSH positions on the Portal-Pack, lapses in communication with stakeholders by both agencies had a negative impact. The problem of coordinating external release of information and agency positions on issues impaired interagency collaboration, contributing to the resulting litigation by the UMWA.

There was a paucity of documented communication between MSHA and NIOSH over the progress of certifying the design changes

made in the Life-Saver 60. However, MSHA Technical Support was informed of the delays in two separate NIOSH communications, although it does not appear that this information was disseminated throughout the entire organization. MSA did not provide monthly progress reports on the production of the Life-Saver 60 to MSHA as agreed. These communication problems contributed to a lack of clarity in the progress of the recall.

Recommendations

We recommend that the Assistant Secretary for Mine Safety and Health ensure, for defects identified in MSHA approved products, that the agency:

1. Develops a process to provide preliminary notification about product defects and immediate actions required to industry officials most directly affected.
2. Develops a system for obtaining prompt feedback on proposed notifications concerning product defects from the responsible SCSR manufacturer.
3. Prepares procedures, consistent with the other recommendations in this section, to clarify the methods, timing and officials responsible for notifying external stakeholders about product defects and recalls.

We also recommend that the Assistant Secretary for Mine Safety and Health in conjunction with the Director, NIOSH, amend the Memorandum of Understanding to specify how the two agencies will ensure that a consistent Federal position is communicated in the future to SCSR industry officials and other external stakeholders.

MSHA Response

"In regard to MSHA approved products, we agree that MSHA should develop a process to provide preliminary notification about product defects and immediate actions required to industry officials most directly affected. The mechanism for this will be a letter from the Assistant Secretary directed to Mine

Operators and Miners with copies sent to other key industry officials. This will be a relatively quick process to notify key stakeholders about problems and immediate required actions. Other items that can be enclosed with the letter include: user notices, approved changes to operations manuals, and other useful information that will help the end user to better address the problem. A Program Information Bulletin (PIB) can be issued later, if necessary, to provide a more detailed explanation of the problem and follow-up corrective actions."

"We agree that MSHA should develop procedures for obtaining prompt feedback on proposed notifications concerning product defects from the responsible Self-Contained Self-Rescuer (SCSR) manufacturer. Manufacturers will be given the opportunity to review notification letters from the Assistant Secretary, PIBs that are in draft status, and other material that is intended to be released by the Agency."

"We agree that MSHA should prepare procedures to clarify the methods, timing and officials responsible for notifying external stakeholders about product defects and recalls. A Task Force will develop standard operating procedures for notifying external stakeholders about product defects and recalls. These procedures will identify the responsibilities of each person involved in MSHA, and timetables for each action."

"We agree that MSHA, in conjunction with the National Institute for Occupational Safety and Health (NIOSH), should amend the Memorandum of Understanding (MOU) to specify how the agencies will ensure that a consistent Federal position is communicated in the future to SCSR industry officials and other external stakeholders. We are currently in the process of modifying the Memorandum of Understanding (MOU) between MSHA and NIOSH. The process for developing unified communications will be addressed in this document."

OIG's Conclusion

We concur with MSHA's proposed corrective actions and consider this recommendation resolved. In order to close this recommendation, please provide us with a memorandum or other documentation of: (1) the new procedure for preliminary

notification; (2) the standard operating procedures developed by the task force for detailing notification of external stakeholders about product defects and recalls; and, (3) a completed MOU with NIOSH for ensuring consistent and unified communications. The MOU should also clarify respective agency roles in communication to external stakeholders.

3. *Quality Assurance*

The need for manufacturers to improve quality assurance practices is a significant factor contributing to the high number of recalls. Insufficient quality assurance by manufacturers is a continuing issue for MSHA and NIOSH as it forces the expenditure of resources on responding to problems rather than preventing them. Under the current regulatory provisions and Memorandum of Understanding, sufficient on-site observations are not being conducted during the manufacture of SCSRs to ensure that the companies' production practices are consistent with their quality control plans and result in products equivalent in quality to the approved prototype models. While the complexity of SCSR technology may reasonably account for a high level of manufacturing defects, the need to recall and/or retrofit, at least once, every SCSR model that uses chemical generation of oxygen and compressed oxygen, warrants increased attention by NIOSH and MSHA to the industry's quality assurance practices.

The historical and continuing problems attributable to the unique SCSR design and manufacturing requirements present substantial challenges to both quality assurance and reliability. According to MSHA officials, the SCSR is on the cutting edge of technology, requiring parts to be compressed into an extremely small container under difficult manufacturing conditions. Current models could be considered almost experimental in nature but the demand from users, including MSHA, is for still smaller and lighter units with advanced features such as voice amplification. Furthermore, it is common for production runs of SCSR models to be completed intermittently, as needed, in view of the relatively limited number of units required to meet customer demand and the service-life of the product. Thus, the incremental improvements in on-going manufacturing processes generally

associated with effective quality control programs cannot be readily applied to the production of SCSRs. To date, every SCSR model that uses chemical generation of oxygen or compressed oxygen has been subject to recall or retrofit. Noted quality expert J.M. Juran in *Quality by Design* (1992, p. 2) states that a general benchmark for "redoing work previously done" in US industry is about one-third. While variation in this number occurs in different industries, a 100 percent recall rate flags the need for a special focus on improving quality and designs for reliability. The more precise and complex designs required by the newest models of SCSRs can be expected to place further pressures on the industry's quality control efforts.

Of the recalls and retrofits OIG examined, virtually all involved issues of inadequate manufacturing quality or design for reliability. Problems of improper design and manufacture are common. Examples of poor quality or design include improperly molded breathing hoses, devices that exploded and SCSR pouches that became too tight to remove the device for usage.

Documents from the NIOSH CQAB clearly raised questions about the adequacy of MSA's quality control in producing the Portal-Pack. A June 27, 1997 letter by a senior NIOSH scientist stated, in regards to the Portal-Pack, that problems with gaps in the filter material and a faulty hinge pin on the firing mechanism "...raise concerns over the adequacy of quality assurance procedures used during production of these SCSR's." The migration of KO₂ chemical dust in the Portal-Pack was only one of several quality assurance problems discovered that were classified as serious defects.

The respective roles of MSHA and NIOSH in certifying the quality assurance practices for SCSRs are contained in 42 CFR 84 and a May 4, 1995 Memorandum of Understanding. Under the regulations, NIOSH is delegated primary responsibility for reviewing manufacturing quality control. However, section three of the Memorandum provides that, while duplication or repetition of audit activities should be avoided, participation on certification and quality assurance is to be done jointly. Item three also states that deficiencies with SCSRs or manufacturing sites will be resolved jointly. The Memorandum lacks specificity to guide MSHA's joint participation with NIOSH in routine manufacturing site inspections.

More frequent on-site reviews of manufacturers' quality assurance practices, effectively scheduled to coincide with the production of SCSRs, could enhance the quality of this equipment and reduce the industry's recall rate. Interviews with SCSR manufacturers, NIOSH and MSHA officials confirmed that the agencies are not jointly conducting frequent manufacturing site reviews during times of production, examining production run data, or systematically applying other common quality assurance techniques. MSHA officials advised that NIOSH schedules the on-site reviews of manufacturers' quality assurance practices and MSHA will participate when NIOSH extends an invitation and the company produces SCSRs for use in mines. Officials of both agencies noted that the scope of their responsibilities place some limits on the resources which can be devoted to a single product. Even so, MSHA and NIOSH officials generally concurred that increasing quality assurance reviews of SCSR manufacturers, especially during production cycles, could improve the quality of SCSRs and reduce resources dedicated to administering future recalls.

Recommendations

We recommend that the Assistant Secretary for Mine Safety and Health in conjunction with the Director, NIOSH, amend the Memorandum of Understanding to:

1. Clarify the respective roles of the agencies with regard to quality assurance; and,
2. Commit the agencies to more frequent on-site reviews of the quality assurance practices of SCSR manufacturers during the production of this equipment.

MSHA Response

"We agree with the recommendation that MSHA and NIOSH should amend the MOU to clarify the respective roles of the agencies with regard to quality assurance and commit the agencies to more frequent on-site reviews of the quality assurance practices of SCSR manufacturers during the production of the equipment. MSHA will conduct audits of each SCSR manufacturer once a year. These audits will be conducted during production runs when possible."

OIG's Conclusion

We concur with the proposed corrective actions and consider this recommendation resolved. In order to close this recommendation, please provide us with a copy of the completed MOU with NIOSH clarifying quality assurance roles and identifying procedures for increasing the frequency of on-site reviews to coincide with production runs.

4. Training Standards

Miners receive an annual training session on SCSRs in order to be able to operate them in a mine emergency. We had two findings with regard to training. First, training conducted for the Portal-Pack recall was not completed within the 30 day time-frame recommended by the manufacturer and approved by MSHA in the July 11, 1997 user's notice. Second, there is significant support within the mining community for increasing the frequency of training on SCSRs beyond just once a year.

Training on the Portal-Pack was not completed within 30 days of the distribution of the user's safety notice. OIG reviewed MSHA's Portal-Pack training records for 111 mines. Of 111 mines, MSHA identified 15 mines (13.5 percent) that did not complete training by October 27, 1997. Mine inspectors visited the mines to specifically confirm training completion in November 1997.

We also found additional problems in MSHA's survey of training compliance related to data collection. MSHA did not collect the dates when training was completed. Implementation of training on the revised procedures within the recommended 30 days could not be fully assessed.

Timely communication of the 30 day deadline for training miners on the new procedures for use of the Portal-Pack through a PIB or other MSHA notification could have strengthened enforcement of training compliance. The Office of Coal Mining Safety and Health (CMS&H) at the Arlington Headquarters has identified noncompliant mines and has taken steps at the district levels

to ensure compliance with all training directives. More active monitoring of noncompliant mines is also being conducted to ensure uniformity of compliance.

Proposed regulations increasing the required frequency of SCSR training will better ensure that miners receive regular instruction in proper SCSR operation. MSHA, NIOSH and the manufacturers noted a need to increase the frequency with which mine owners conduct training on the use of SCSRs. We found substantial support among many of those interviewed regarding the need to augment SCSR training standards to address concerns about sufficiency.

It has been suggested that training on these units could coincide with safety and fire training which is held every 90 days. Although changes in the frequency of training have already been proposed by MSHA, efforts are moving slowly. Recent decisions by MSHA to allow commingling of different models of SCSRs, increases the need for more frequent training efforts to ensure that miners can properly operate multiple models of devices in a mine emergency.

Recommendations

We recommend that the Assistant Secretary for Mine Safety and Health ensure that MSHA:

1. Reviews the frequency and type of training required to ensure that miners will be able to effectively use SCSRs in an emergency.
2. Expedites changes in the regulations to require SCSR training as determined necessary.

MSHA Response

"We agree with the recommendation that MSHA should review the frequency and type of training required to ensure that miners will be able to effectively use SCSRs in an emergency. It will be necessary for MSHA, in conjunction with NIOSH, to conduct more research to determine the optimum frequency for retraining. We will use this information along with the

results of previous research conducted by the Bureau of Mines in our decision-making process. If it is determined that changes in existing regulations are needed, an expeditious process will be followed to make changes to regulations as necessary."

OIG's Conclusion

We concur with MSHA's proposed corrective actions and consider this recommendation resolved. In order to close this recommendation, please provide a memorandum directing the initiation of a review to investigate the optimal type and frequency of training required to ensure that miners will be able to effectively use SCSRs in an emergency.

5. Standards for Certification and Audit

Opportunities exist for improving the standards used in the certification and audit of SCSRs. Specifically, we identified two areas for improvement. First, MSHA should expedite its pursuit of legislative changes to require environmental testing prior to certification of equipment to improve SCSR reliability. Second, MSHA and NIOSH need to review and update audit sampling procedures, tests and acceptable parameters for tests used in certification.

MSHA and SCSR manufacturers agreed in interviews that units need to be subjected to more realistic testing to replicate mining conditions during certification. The CSE and MSA corporations state that they now conduct environmental testing, however, no minimum standards govern the types of testing performed. There is no assurance that environmental testing conducted by manufacturers are optimized toward simulating actual usage.

OIG reviewed 35 cases involving problem issues with SCSRs over the last 12 years. The source of the data was case files archived at the MSHA Approval and Certification Center. In 8 of 13 recall or retrofit cases, we found that problems could have been detected and corrected more effectively if environmental testing had been conducted with prototypes and a more effective sampling of production units had been done. Currently MSHA/NIOSH only conducts environmental testing

through an audit program of a small number of units which have been certified.

Our review found that the audit program sampling procedures need to be reviewed to ensure that they are optimal, given the limited resources available. Concerns were raised in interviews with MSHA technical experts that the audit program proportional sampling being used could be improved. For example, greater consideration could be given to organizing the proportional sampling according to new information becoming available on the status of SCSRs among stored, cached, machine mounted or worn status. Conducting a proportional sample simply based on the model population may not be the best sampling method. Priority in the sample could be given to SCSRs that are worn or machine mounted and, therefore, subject to greater wear and tear.

Manufacturers stated that different testing equipment at various testing sites may not be calibrated or used consistently to certify or audit their equipment. We found that different testing equipment and technicians are being used at testing sites within NIOSH. While the PRL and the CQAB have different roles, calibration of equipment and testing procedures do not appear to be closely coordinated. CSE and MSA stated that while their prototype models passed company tests designed to reproduce tests used in certification, the prototypes did not pass tests conducted by NIOSH.

There was also concern expressed that breathing tests with human test subjects do not allow for a reasonable range of human responses. SCSRs would pass manufacturer breathing tests but then fail with a NIOSH test subject. The test could establish more empirical parameters to benefit SCSR design and development and avoid the appearance of subjectivity.

NIOSH acknowledged that testing standards are not always expressed in scientific formula. This makes it difficult for manufacturers to reproduce tests for design and product development. An example provided by the manufacturers for needed scientific formulas is in the area of vibration testing. Manufacturers want vibration testing standards expressed with vibration tables rather than just time on a rotop machine so that standards can be reproduced.

Reviewing whether equipment is calibrated accurately and used

consistently across sites is complex and highly technical. We did not find strong linkages between the PRL and the CQAB testing facilities that would ensure consistency of equipment and testing procedures. MSHA could initiate a collaborative ad hoc committee comprised of NIOSH and MSHA technical experts to test equivalency of calibration in equipment and adopt standard testing procedures. Procedures governing operation of testing equipment should be standardized. The goal of the committee would be to issue a report making recommendations in these areas.

We have identified areas of testing and certification that could benefit from MSHA/NIOSH review. Environmental testing is needed as part of the certification to reduce the number of recalls. Areas of sampling, calibration and use of testing equipment across sites require review to improve regulatory effectiveness.

Recommendations

1. We recommend that the Assistant Secretary for Mine Safety and Health and the Director, NIOSH, under the agencies' Memorandum of Understanding, form a joint ad hoc committee to review audit sampling, calibration and consistent usage of testing equipment.
2. We also recommend that the Assistant Secretary for Mine Safety and Health encourage the Director, NIOSH, to expedite a legislative proposal to mandate environmental testing as part of the certification procedure in 42 CFR 84.

MSHA Response

"We agree with the recommendation that MSHA and NIOSH, under the agencies' MOU, should form a joint ad hoc committee to review audit sampling, calibration and consistent usage of testing equipment. This committee will be formed utilizing a cross section of all MSHA personnel involved in the SCSR approval and enforcement program. The committee will be tasked with reviewing the audit sampling program, and the calibration and consistent usage of testing equipment.

"We agree that MSHA should encourage NIOSH to expedite a

legislative proposal to mandate environmental testing as part of the certification procedures in Title 42, Code of Federal Regulations, Part 84. The Assistant Secretary will communicate this to the Director of NIOSH. A joint committee consisting of MSHA and NIOSH representatives have, among other things, already addressed this."

OIG's Conclusion

We concur with MSHA's proposed corrective actions and consider this recommendation resolved. Due to the need for participation of NIOSH in implementing this recommendation, and in consideration of current NIOSH disagreement with the formation of an ad hoc committee to review audit sampling, calibration and consistent usage of testing equipment, we agree that the implementation of an ad hoc committee can wait until after NIOSH has completed an internal review. Since the field visits conducted to complete this report, NIOSH has initiated action to optimize the collaboration between the PRL and the CQAB by initiating an examination to redefine their roles and responsibilities.

In order to close this recommendation, please provide us with a copy of the MOU and documentation of MSHA's request to NIOSH that NIOSH expedite a legislative proposal to mandate environmental testing as part of the certification procedures in Title 42, Code of Federal Regulations, Part 84.

6. Developing Information Resources

Our review found that insufficient information on the numbers and location of Portal-Packs in the mines was due, in part, to MSHA's dependence on MSA for information and the need to increase information resources. In addition, we found that current MSHA data collection efforts need review. The inaccurate estimates of the numbers and use of Portal-Packs in the mines hampered MSHA's effectiveness in administering the recall. MSA initially reported to MSHA that an estimated 5,490 Portal-Packs were in use on August 15, 1997. On November 14, 1997, 7,533 units were discovered, which represents a percent

change increase of 37 percent. This discrepancy exceeded the 20 to 28 percent range of variances between initial estimates and actual numbers of SCSRs recalled in the other cases we reviewed.

The May 4, 1995 memorandum of understanding between MSHA and NIOSH states that MSHA needs to be able to determine the numbers and usage of deficient SCSR models deployed in the mines. To adequately execute this responsibility, conducting ongoing SCSR data collection is necessary. Lacking current information on the numbers and usage of the Portal-Pack had negative implications for the recall.

Limited information on the numbers and usage of the Portal-Pack in the mines impeded an accurate proportional audit of the different categories of cached, machine mounted and miner worn units which have varying degrees of risk for deficiency. Lack of information also resulted in a six-month delay in accurately determining the numbers of units in the mines and contributed ambiguity in assessing the extent of the problem. MSHA's recent change in decreasing the time allowed for correcting deficiencies through recall or retrofit, increases the importance of maintaining accurate current data on the numbers, location and usage of SCSRs.

Due to the limitations imposed by the marketplace, depending on companies for information on the number and location of SCSRs is not a sound operating procedure. CSE, Drager, Ocenco, and MSA stated that they are only able to maintain rough estimates of the numbers and location of SCSRs, as they make significant portions of SCSR sales to distributors who will not reveal subsequent customer information. Sales through distribution networks, subsequent transportation of SCSRs by mining companies and other sources of relocation inhibit accurate tracking from beyond where the SCSR was sold.

CMS&H has initiated efforts to improve data collection regarding SCSRs. CMS&H is collecting data that has a direct bearing on SCSR use within the mine, such as average mining height in inches, the travel distance from the point of deepest penetration in the mine to the surface in feet, commingling of different models of SCSRs, and other critical safety information requiring continuous review and analysis. Because of the constant physical changes in mining conditions, CMS&H estimates that the data they are collecting has utility for a

maximum of six-months, after which it becomes gradually obsolete. Our review supports the new information collection activity as essential to MSHA's regulation, but also recognizes the need to increase the frequency of this effort.

CMS&H officials stated that they have not reviewed the data collection form with internal MSHA experts or tested the survey with a sample of inspectors who will obtain the information from the mines and complete the form. Pilot testing a data collection form with a sample of those expected to complete it ensures the clarity of the questions and should result in more accurate and consistent data.

In summary, we found that insufficient information on the Portal-Packs in the mines contributed to the difficulty of the recall. We suggest that current data collection efforts need to be increased and that methods should be reviewed.

Recommendations

We recommend that the Assistant Secretary for Mine Safety and Health ensure that:

1. CMS&H's data collection activities be pilot tested with MSHA districts for receiving editorial feedback.
2. CMS&H increase the frequency of surveying SCSRs and coal mining conditions to twice a year for development of adequate information resources.

MSHA's Response

"We agree that MSHA's Coal Mine Safety and Health (CASH) data collection activities regarding SCSRs should be pilot tested with the MSHA Districts for the purpose of receiving editorial feedback. This will be accomplished before the next survey is conducted, which is currently scheduled to begin in April 1999. MSHA initiated the initial survey due to an immediate need of

the information. Subsequently, we have met with MSHA inspection supervisors and inspector representatives to discuss the continued need for this type of information. As a part of that process the SCSR data collection Form was revised, and includes instructions on how to complete the Survey Form. This revised Form is currently under review by the National Council of Field Labor Locals. Upon final approval, CASH plans on sending the revised Form to the Districts and requests that at least one inspector per District conduct a survey, complete the Form, and provide feedback to Headquarters on any changes that need to be made to revise the Form to accurately capture the information needed."

"We also agree that there is a need for MSHA to conduct a survey to more accurately assess SCSR use and mining conditions affecting escape. Although mine operators do change the types of SCSR protection they provide, and mining conditions are continually changing, MSHA believes that an annual survey would capture this information and would provide the necessary information needed to assess the scope of any potential problems. However, we will evaluate the information we receive during our next survey, currently scheduled to be conducted during the 3rd quarter of FY 1999, and compare this information with data from the survey that was completed in FY 1998. If this information indicates significant changes have taken place since the FY 1998 survey, MSHA will modify the annual survey requirement accordingly."

OIG's Conclusion

On the basis of MSHA's response, we consider this recommendation resolved. To close this recommendation, we would appreciate receiving a copy of the new survey form and a memo directing survey operations be performed once a year. The memo should direct that an assessment be conducted as to whether an increase in survey frequency is needed based on changes in conditions from 1998 to 1999. We agree that the decision to expand survey operations to twice a year needs to be supported by data findings.

7. An MSHA Focal Point for SCSR Recalls

The recent reorganization to develop a focal point for handling recalls has not been fully completed. The reorganization was conducted to ensure a seamless transfer of responsibilities and efficient administration of recalls. Specifically, MSHA did not have designated personnel dedicated to conducting recalls or establish clear contact points for communication so that operations were optimally organized. NIOSH, MSHA and corporate interviewees complained that a focal point for conducting recalls was lacking.

While the reorganization is a positive development for efficiency reasons, additional details require clarification. In particular, the new position description for the persons delegated to handle SCSR recalls needs to be revised to reflect new responsibilities and duties. SCSR recalls are not "special projects," which is the description of the current assignment, but a regularly recurrent part of MSHA activity. Dedicated personnel and resources for this ongoing effort require identification.

We found that policies and procedures that existed before the reorganization lacked specificity and need updating to reflect changes in the way that recalls are handled. Aspects of communication and coordination with NIOSH also need to be clarified. Policies and procedures need to be written in order to protect against vulnerabilities presented by personnel changes.

Technical Support Division management has verbally promised personnel and technical resources to support recalls. However, policies and procedures should be developed to identify the specific staff who will be responsible for recalls and to clarify the details as to how A&CC will provide support to MSHA's Pittsburgh and Safety and Health Technology Center. An organizational chart could provide further clarification. Without such policies and plans, MSHA is vulnerable to personnel changes and recall knowledge being concentrated in one individual.

Recommendations

We recommend that the Assistant Secretary for Mine Safety and

Health ensure that MSHA:

1. Develop written policies and procedures incorporating the A&CC Division and the Pittsburgh and Safety and Health Technology Center which specify responsibilities for conducting recalls and the A&CC resources to be shared.
2. Revise the position description for the employee assigned responsibility for recalls to reflect the new responsibilities and priorities established by the reorganization.

MSHA Response

"We agree with the recommendation for MSHA to develop written policies and procedures incorporating both its Approval and Certification Center (A&CC) Division and the Pittsburgh Safety and Health Technology Center. These policies and procedures will be developed specifying the responsibilities for conducting recalls and the A&CC resources that will be shared, In addition, an organizational chart will be developed which further illustrates the responsibilities during SCSR investigations."

"We also agree that the position description for the employee assigned the responsibility for SCSR recalls, Dr. Jeffery Kravitz, should be revised to reflect the new responsibilities and priorities established by the organization. Dr. Kravitz's position description will be revised from "Chief, Special Projects" to adequately reflects new responsibilities while integrating these with other existing responsibilities including Mine Emergency Operations and Mine Emergency Response Training."

OIG's Conclusion

We concur with MSHA's proposed corrective actions and consider this recommendation resolved. In order to close this recommendation, please provide us with the new written policies and procedures, a revised organizational chart and the new position description.

Major Contributors to this Report:

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* * *

In preparation of this report we solicited comments from the National Institute of Occupational Safety and Health. The NIOSH comments can be found in Appendix C. We have responded to NIOSH comments in a letter located in Appendix D. We appreciate NIOSH's cooperation during this evaluation, as well as their contributions to the final report to MSHA.

Appendix

Glossary

A&CC	MSHA Approval and Certification Center in Triadelphia WV
Bituminous Coal Association	Industry association for coal mines
Bruceton	Location of MSHA facility in PA located on the grounds of the NIOSH PRL
CASH	MSHA Coal Mine Safety and Health
CBD	Commerce Business Daily
CFR	Code of Federal Regulations
CMS&H	The Office of Coal Mining Safety & Health
CSE	Manufacturer of self-contained self-rescuers
DOL	Department of Labor
Drager	Manufacturer of self-contained self-rescuers
GAO	General Accounting Office
MSHA	Mine Safety and Health Administration
PRL	NIOSH Pittsburgh Research Laboratory
SCSR	Self-Contained Self-Rescuer

MSA	Mine Safety Appliance Company - Manufacturer of self-contained self-rescuers
Morgantown	NIOSH WV facility
OACE	Office of Analysis, Complaints and Evaluation
OIG	Office of the Inspector General
NIOSH	National Institute of Occupational Safety and Health
Ocenco	Manufacturer of self-contained self-rescuers
PIB	Program Information Bulletin
PRB	DOL Procurement Review Board
PRL	NIOSH Pittsburgh Research Laboratory
UMWA	United Mine Workers Union
CQAB	NIOSH Certification and Quality Assurance Branch



NOV 16 1998

MEMORANDUM FOR F.M. BROADAWAY
Assistant Inspector General for Analysis,
Complaints and Evaluations

FROM:

J. DAVITT McATEER *J. Davitt McAteer*
Assistant Secretary for
Mine Safety and Health

SUBJECT:

Review of a Self-Contained Self-Rescuer
Procurement Contract and the Portal-Pack
Recall - Draft Report No. 16-OACE-98-MSHA

This is in response to your memorandum of October 9 with the attached subject draft report. We have thoroughly reviewed the report and agree with its stated conclusions and recommendations. Following are some minor technical corrections, our response to each of the recommendations, and the corrective actions we will implement to satisfactorily address these recommendations:

Technical Corrections

The date "November 13, 1987" on the bottom of page 6 should be "November 13, 1997".

References to a "voice actuation" feature on page 11 of the report should be revised to be "voice amplification". The reference to "CO₂" should be changed to "CO".

In the first paragraph on page 17, on line 13, the phrase "the need to recall and retrofit" should be changed to "the need to recall and/or retrofit". In the second paragraph on the same page, on line 18, the word "recall" should be changed to "recalled or retrofitted". Also, in the same paragraph, on line 22, the word "recall" should be changed to "recall/retrofit".

Responses to Recommendations and Corrective Actions

1. We agree that the Mine Safety and Health Administration (MSHA) should review sole-source procurement practices to expand the use of competitive bids and ensure conformance with the Department of Labor (DOL) regulations. MSHA has always and will continue to foster competition to the

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maximum extent possible by awarding contracts based on full and open competition. In the case of sole-source procurement actions, any proposed contract in excess of \$25,000, to be awarded on the open market, is synopsized in the Commerce Business Daily (CBD). The purpose of the CBD announcement is to afford other offerors the opportunity to make the MSHA contracting officer aware of an equivalent product or service that their firm/organization has to offer. When that situation occurs, the MSHA contracting officer then affords that firm/organization the opportunity to make an offer by providing them with a solicitation document, in accordance with the requirements of both Federal and DOL Acquisition Regulations.

2. In regard to MSHA approved products, we agree that MSHA should develop a process to provide preliminary notification about product defects and immediate actions required to industry officials most directly affected. The mechanism for this will be a letter from the Assistant Secretary directed to Mine Operators and Miners with copies sent to other key industry officials. This will be a relatively quick process to notify key stakeholders about problems and immediate required actions. Other items that can be enclosed with the letter include: user notices, approved changes to operations manuals, and other useful information that will help the end user to better address the problem. A Program Information Bulletin (PIB) can be issued later, if necessary, to provide a more detailed explanation of the problem and follow-up corrective actions.
3. We agree that MSHA should develop procedures for obtaining prompt feedback on proposed notifications concerning product defects from the responsible Self-Contained Self-Rescuer (SCSR) manufacturer. Manufacturers will be given the opportunity to review notification letters from the Assistant Secretary, PIBs that are in draft status, and other material that is intended to be released by the Agency.
4. We agree that MSHA should prepare procedures to clarify the methods, timing and officials responsible for notifying external stakeholders about product defects and recalls. A Task Force will develop standard operating procedures for notifying external stakeholders about product defects and recalls. These procedures will identify the responsibilities of each person involved in MSHA, and timetables for each action.

5. We agree that MSHA, in conjunction with the National Institute for Occupational Safety and Health (NIOSH), should amend the Memorandum of Understanding (MOU) to specify how the agencies will ensure that a consistent Federal position is communicated in the future to SCSR industry officials and other external stakeholders. We are currently in the process of modifying the Memorandum of Understanding (MOU) between MSHA and NIOSH. The process for developing unified communications will be addressed in this document.
6. We agree with the recommendation that MSHA and NIOSH should amend the MOU to clarify the respective roles of the agencies with regard to quality assurance and commit the agencies to more frequent on-site reviews of the quality assurance practices of SCSR manufacturers during the production of the equipment. MSHA will conduct audits of each SCSR manufacturer once a year. These audits will be conducted during production runs when possible.
7. We agree with the recommendation that MSHA should review the frequency and type of training required to ensure that miners will be able to effectively use SCSRs in an emergency. It will be necessary for MSHA, in conjunction with NIOSH, to conduct more research to determine the optimum frequency for retraining. We will use this information along with the results of previous research conducted by the Bureau of Mines in our decision-making process. If it is determined that changes in existing regulations are needed, an expeditious process will be followed to make changes to regulations as necessary.
8. We agree with the recommendation that MSHA and NIOSH, under the agencies' MOU, should form a joint ad hoc committee to review audit sampling, calibration and consistent usage of testing equipment. This committee will be formed utilizing a cross section of all MSHA personnel involved in the SCSR approval and enforcement program. The committee will be tasked with reviewing the audit sampling program, the long term field evaluation program, and the calibration and consistent usage of testing equipment.
9. We agree that MSHA should encourage NIOSH to expedite a legislative proposal to mandate environmental testing as part of the certification procedures in Title 42, Code of Federal Regulations, Part 84. The Assistant Secretary will communicate this to the Director of NIOSH. A joint committee consisting of MSHA and NIOSH representatives have, among other things, already addressed

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the need to include environmental testing in regulations. This will be formally addressed by the ad hoc committee mentioned in item 8.

10. We agree that MSHA's Coal Mine Safety and Health (CMSH) data collection activities regarding SCSRs should be pilot tested with the MSHA Districts for the purpose of receiving editorial feedback. This will be accomplished before the next survey is conducted, which is currently scheduled to begin in April 1999. MSHA initiated the initial survey due to an immediate need of the information. Subsequently, we have met with MSHA inspection supervisors and inspector representatives to discuss the continued need for this type of information. As a part of that process the SCSR data collection Form was revised, and includes instructions on how to complete the Survey Form. This revised Form is currently under review by the National Council of Field Labor Locals. Upon final approval, CMSH plans on sending the revised Form to the Districts and request that at least one inspector per District conduct a survey, complete the Form, and provide feedback to Headquarters on any changes that need to be made to revise the Form to accurately capture the information needed.
11. We also agree that there is a need for MSHA to conduct a survey to more accurately assess SCSR use and mining conditions affecting escape. Although mine operators do change the types of SCSR protection they provide, and mining conditions are continually changing, MSHA believes that an annual survey would capture this information and would provide the necessary information needed to assess the scope of any potential problems. However, we will evaluate the information we receive during our next survey, currently scheduled to be conducted during the 3rd quarter of FY 1999, and compare this information with data from the survey that was completed in FY 1998. If this information indicates significant changes have taken place since the FY 1998 survey, MSHA will modify the annual survey requirement accordingly.
12. We agree with the recommendation for MSHA to develop written policies and procedures incorporating both its Approval and Certification Center (A&CC) Division and the Pittsburgh Safety and Health Technology Center. These policies

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and procedures will be developed specifying the responsibilities for conducting recalls and the A&CC resources that will be shared. In addition, an organizational chart will be developed which further illustrates the responsibilities during SCSR investigations.

13. We also agree that the position description for the employee assigned the responsibility for SCSR recalls, Dr. Jeffery Kravitz, should be revised to reflect the new responsibilities and priorities established by the organization. Dr. Kravitz's position description will be revised from "Chief, Special Projects" to a new description which adequately reflects his new responsibilities while integrating these with other existing responsibilities including Mine Emergency Operations and Mine Emergency Response Development Training.

We thank you for the opportunity to review and comment on the subject draft report. We always welcome any constructive criticism which will enable us to do a better job protecting the safety and health of our Nation's miners. If you have any questions concerning our comments, please contact Mr. Michael J. Lawless at (703) 235-1580.

Attachment



National Institute for
Occupational Safety and Health
Centers for Disease Control
and Prevention (CDC)
200 Independence Avenue, SW
Washington, DC 20201

November 5, 1998

F. M. Broadaway
Assistant Inspector General for
Analysis, Complaints and Evaluations
U.S. Department of Labor
Office of Inspector General
Washington, D.C. 20210

Dear Mr. Broadaway:

Thank you for the opportunity to comment on the draft Report 16-OACE-98-MSHA prepared by the Office of Inspector General (OIG) for the Department of Labor. Many of the recommendations in the report are excellent and are consistent with the interests of the National Institute for Occupational Safety and Health (NIOSH) in improving our Certification and Long-Term Field Evaluation Programs. However, there are several misconceptions and inaccuracies in the report that should be clarified and/or corrected. Our comments are contained in the attachment and are divided in two separate categories: Section 1 contains comments on the report's misconceptions and inaccuracies, and Section 2 provides comments on the recommendations.

NIOSH has already initiated several activities that address the OIG recommendations. We are examining the roles and responsibilities of our Pittsburgh Research Laboratory (PRL) and our Morgantown Certification and Assurance Branch (CQAB) laboratories and are developing appropriate processes and procedures to assure effective collaboration. A joint NIOSH/ Mine Safety and Health Administration (MSHA) team examined the Self Contained Self Rescuer (SCSR) Program and drafted recommendations for improvement. Many of these recommendations are consistent with the suggestions of the OIG. NIOSH is planning to propose new quality assurance standards for all NIOSH certified respirators which will also improve the quality of SCSR products. MSHA will be invited to assist in finalizing these draft standards for inclusion into 42.CFR Part 84.

Page 2 - Mr. Broadway

I appreciate your assistance in helping the agencies identify ways in which we can improve our programs and protection for workers.

Sincerely yours,

A handwritten signature in black ink, appearing to read "L. Rosenstock".

Linda Rosenstock, M.D., M.P.H.
Director

Enclosure

Section I, Misconceptions and Inaccuracies

1. NIOSH SCSR Programs, Roles and Responsibilities

In general, the recommendations are consistent with NIOSH goals and objectives. However, several descriptions of NIOSH programs and corresponding OIG conclusions are inaccurate. Correction of the misconceptions of these programs is important because these misconceptions impact some of the report's conclusions. Their correction will therefore better focus resources and identify program activities needing improvement.

The report makes no distinction between two NIOSH programs relating to Self-Contained, Self Rescuers (SCSRs), certification and research. We believe that misconceptions expressed in the report are largely due to confusion or misunderstanding of the following NIOSH activities: certification, quality assurance audit, field evaluation, and environmental testing. The NIOSH SCSR certification and research programs were developed independently in two government organizations, the US Bureau of Mines and NIOSH. Recent Congressional legislation combined these organizations and provides NIOSH an opportunity for improving the effectiveness of these programs. Both certification and research programs are vital in providing SCSRs that meet 42 CFR Part 84 (42CFR84) standards and assure protection for workers by identifying defective SCSRs.

The Certification and Quality Assurance Branch (CQAB), at the Appalachian Laboratory for Occupational Safety and Health, Morgantown, West Virginia, has the authority and responsibility to interpret and implement the 42CFR84 design, quality assurance and performance regulatory standards. CQAB performs certification tests, manufacturing-site quality assurance audits, and product audits including SCSR audits, according to federal regulations contained in 42CFR84. In addition, CQAB conducts investigations to determine SCSR compliance to certification standards. These procedures are documented in the Certified Product Investigation Process (CPIP) standard operating procedures.

The Pittsburgh Research Laboratory (PRL) is responsible for human physiology research, SCSR technology research, environmental testing and evaluation of field deployed SCSRs. The SCSR environmental tests and the Long-Term Field Evaluation Program (LTFE) standards and tests are not part of the process of approving or certifying respirators according to the standards set out in 42CFR84 and are not quality assurance audits to determine compliance with the certification standards. The PRL LTFE program is a reliability assurance evaluation to determine the effect of mine environment and aging on SCSR performance. The test standards and protocol for the LTFE are not correlated to or part of the 42CFR84 certification standards and have been periodically adjusted to address specific research interests of the laboratory. PRL's environmental tests are also not part of the 42CFR84 certification requirements. These environmental tests were initiated in research projects relating to SCSR technology development and evaluation and were conducted independent of certification requirements, and manufacturers' SCSR product developments. The tests represent an evaluation standard that has not received critical examination or public comment required for a regulatory standard. The environmental conditioning portion of the environmental evaluation performed on newly

certified SCSRs which were developed and approved independent of the PRL environmental standard has not revealed any of the design or performance problems that resulted in recall. However, baseline testing done for the environmental evaluation of the MSA Life-Saver 60 did reveal a problem with the adhesive used to bond the breathing bag to the unit that did result in recall. Environmental evaluations are important, but the current PRL environmental challenge should be fully developed and incorporated into a reliability standard that is related to a specific length of in-mine service.

The OIG report did not recognize the respective and distinct roles of the CQAB and the PRL programs. Because of these distinctions, there are a number of OIG conclusions and suggestions relating to the two NIOSH laboratories that NIOSH believes to be in error.

The OIG report (page 16) indicates "Environmental testing is needed as part of the certification to reduce the number of recalls." NIOSH agrees that environmental testing can improve product reliability if the environmental tests and standards are properly defined, but we disagree with the basis for this conclusion. The OIG on page 17 of its draft report correctly states that "virtually all" of the recalls and/or retrofits involved manufacturing or product quality problems. Environmental testing will not prevent the product quality errors. To address improvements needed in product quality, NIOSH is in the process of drafting new quality assurance standards for incorporation into 42CFR84. These new standards will substantially improve product quality and hopefully reduce the need for further recalls. NIOSH believes, however, that environmental testing can be an important tool for improving product reliability. Reliability assures that a product performs as intended by the design, under specified conditions of use, and for a specified duration. On the other hand, quality assurance ensures that each new product manufactured conforms to specifications.

The OIG report states that (page 20) "We found that potentially 60 percent of the problems could have been detected and corrected prior to certification if environmental testing had been in place." We disagree with this OIG conclusion and are not aware of the data used to support it. It is the LTFE program, not the environmental tests, that has successfully identified a number of quality and reliability problems in SCSRs. While we disagree with this OIG conclusion, we agree that environmental tests can be an important tool for improving SCSR reliability. NIOSH is interested in upgrading the 42CFR84 certification standards addressing performance, quality assurance and reliability standards.

Increasing the number of product audits conducted by CQAB will be helpful in identifying quality problems in a manner consistent with 42CFR84 standards. This will address the concerns expressed by the OIG (page 21) relating to "consistency of equipment and test procedures" between PRL and CQAB. NIOSH does not agree with the OIG suggestion (page 21) that "MSHA could initiate a collaborative ad hoc committee comprised of NIOSH and MSHA technical experts to test equivalency of calibration in equipment and adopt standard testing procedures." The two NIOSH programs have different responsibilities. The PRL equipment and test program are not linked to requirements of 42CFR84; CQAB's are. However, NIOSH realizes the potential benefits of optimizing the collaboration of these two unique laboratory programs and is in the process of examining and redefining their roles and responsibilities.

2. NIOSH failure to expedite MSA certification extension application

The OIG report has several references to the claim that NIOSH failed to prioritize the MSA certification extension application including pages 7, 10, and 16. NIOSH gives processing priority to a certification extension application involving any respirator non-conformance. The CPIP procedures describe the priority for processing certification extension applications to assure that non-conformances are expeditiously processed and that respirator equipment is returned to its approved condition in a timely manner. This procedure also requires expediting applicable tests, examining QA documentation, and completing other administrative requirements mandated by 42CFR84. The MSA Life-Saver 60 certification extension application was prioritized and processed by NIOSH in the required "expeditious" manner. Delays are attributable to the manufacturer. Despite recommendations by NIOSH to address only the nonconformance which would not require testing, the manufacturer's application contained product and documentation changes beyond those needed to address the nonconformance. The additional product changes were suggested by MSHA. The additional product changes caused a substantial delay in MSA having products available to test and in submitting acceptable documentation in a complete application. In establishing priorities, NIOSH does not wave 42CFR84 requirements.

While we agree that communications between NIOSH and MSHA could be improved, we disagree with the OIG remark (page 16) "There was also a breakdown of communication between MSHA and NIOSH over the progress of certifying the design changes made in the Life-Saver 60." Our records indicate that communications were appropriate and frequent between the responsible officials in both agencies with regard to the MSA certification extension application.

Section 2, Recommendations

There are a number of recommendations which NIOSH accepts and are consistent with internal recommendations made by a joint NIOSH/MSHA Team. The team draft report identifies many of the same opportunities for improvement identified in the OIG report. There is general agreement that collaboration, coordination, and communications between NIOSH and MSHA, and among the organizational units in these agencies could be improved. NIOSH agrees that a more detailed Memorandum of Understanding (MOU) should be jointly developed to address these improvements. In addition, NIOSH believes that several policies relating to investigations of product non-conformances and informing the public of recalls/retrofits need to be redefined. NIOSH further agrees that 42CFR84 standards and tests need to be improved relative to product performance, quality and reliability.

The following comments address the OIG recommendations.

1. Procurement Contract

The recommendations on page 12 are directed to MSHA. NIOSH has no comment.

2. Communications

NIOSH agrees that it is necessary to develop jointly with MSHA documented policies and practices for (page 12) "...timely and accurate notifications of product defects, policies and

procedures to clarify responsibilities for disseminating information, and the effective coordination of official positions...". NIOSH strongly suggests that these documented policies, procedures, etc. be jointly established. Many of the jointly NIOSH/MSHA certified respirators are used in several industries and other countries. NIOSH has a vital role in the timely and accurate sharing of information beyond the mining industry.

NIOSH is in the process of clarifying roles and responsibilities for CQAB and PRL to assure effective collaboration and optimal use of these unique laboratories and expertise.

While the recommendations on page 16 are directed to the Assistant Secretary for MSHA, NIOSH recognizes the necessity for the processes, systems, and procedures to be jointly developed. In conjunction with MSHA, NIOSH will also jointly establish an MOU to be consistent with these program guides.

3. Quality Assurance

NIOSH has prepared new (pre-decisional draft) quality assurance standards intended to be used for all NIOSH certifications. The draft includes enhanced standards from a variety of sources including MSHA standards contained in 30CFR. NIOSH agrees with the recommendations on page 18 and 19, that the roles of the agencies with regard to quality assurance need to be clarified, and that more frequent manufacturing-site monitoring must be accomplished. NIOSH agrees to seek input from MSHA for the new quality assurance standards.

4. Training Standards

While the training recommendations are addressed to MSHA, NIOSH recognizes that training relating to the donning and use of SCSRs is extremely important to assuring worker protection and a successful mine egress during emergencies. Therefore, NIOSH offers to assist MSHA in sharing research information and/or conducting research to improve SCSR protection for workers.

5. Standards for Certification and Audit

Several misconceptions and inaccuracies in the OIG report are noted and corrected above. However, NIOSH recognizes the need for improved performance, quality, and reliability assurance standards and as discussed above NIOSH intends to prepare improved standards for inclusion in 42CFR84. NIOSH further will jointly establish with MSHA the new policies, processes, procedures and MOU to address the needed improvements.

6. Developing Information Resources

While the recommendations on page 23 are directed to MSHA, NIOSH recognizes the importance of field data to assure SCSR performance and reliability. As noted previously in these comments, reliability assurance involves performance intended by a product design, for a specified duration, under specified conditions of use. The conditions and duration of SCSR field use and deployment are vitally important components of assuring product reliability. Only the user can assure that the SCSR is maintained in accordance with the manufacturer's conditions of use and duration. MSHA could assure that workers are informed and trained in the handling, use and storage of SCSRs. These field aspects of SCSR protection are not under the control of the

manufacturer and are the responsibility of the user.

7. An MSHA Focal Point for SCSR Recalls

These recommendations relating to effective coordination of recalls/retrofits and documented procedures are directed to MSHA. However, NIOSH recognizes that the procedures and structure assuring effective coordination within each agency affects the performance of both agencies and their ability to accomplish SCSR program objectives. Therefore, NIOSH and MSHA need to define their internal processes, procedures, etc. and jointly assure that the interagency MOU appropriately addresses the needed coordination.



MAR 31 1999

Dr. Linda M. Rosenstock
Director
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention
200 Independence Avenue, SW
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Dear Dr. Rosenstock,

Thank you for comments and contributions of November 5, 1998 on the report "Review of a Self-Contained Self-Rescuer Procurement Contract and the Portal-Pack Recall for the Mine Safety and Health Administration." Many of the NIOSH comments have been incorporated into the attached final report. We have reviewed the major remaining points of disagreement raised by NIOSH and respond to these below.

NIOSH discusses product quality and reliability as having different meaning in the context of recommending environmental testing. We find that our difference on this issue is related to how product quality and product reliability are defined, with differences arising from operational and conceptual meanings of quality. To avoid confusion on this point we have discussed quality and reliability separately where possible, although we define quality as including issues of manufacturing, product reliability and design. We conclude that environmental testing would be effective in improving product quality, as part of a testing program including prototype and production models.

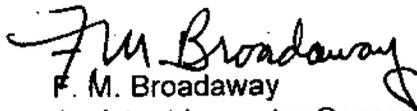
NIOSH disagreed with our conclusion that 60% of the SCSR problems could have been detected and corrected prior to certification if environmental testing had been in place. We have clarified our finding. Environmental testing with prototypes and production units selected by more effective sampling methods, could improve certification and SCSR surveillance. The source of our data was archived case files from the MSHA Technical Support Center.

NIOSH disagreed that they did not expedite certification of the Life-Saver 60. We find that NIOSH, MSHA and MSA anticipated at a August 22, 1997 meeting that NIOSH certification of the Life Saver 60 would be expedited so that production could begin soon. The unit had been previously certified. The NIOSH correspondence we reviewed indicated that the delay was caused by requesting document changes. Despite the urgency involved in certifying the unit so that it could go into production, it was not certified for over two months.

NIOSH disagreed over whether a breakdown of communications between NIOSH/MSHA occurred in certifying the design changes made in the Life-Saver 60. Upon review, we find that although there was limited documented communication between NIOSH and MSHA on this issue, MSHA should have known about the delays in certification and production. We have amended this part of this report.

Again, we want to thank you for your assistance and cooperation on this project.

Sincerely,



F. M. Broadaway
Assistant Inspector General for Analysis,
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